TABLE 3-continued

Summary of Preliminary Results of Phase 1 Clinical Trial of Oral Gossypol for Adrenocortical Cancer

Age/Sex	Site	Dose	Duration	Level	Side Effects	Response
26/M	Lung Liver	70	3 weeks	1,025	Xerostomia Nausea Transaminitis	Progression
52/F	Abdomen	40	6 weeks	444	Xerostomia Fatigue Nausea	Partial Response
34/M	Abdomen Liver	40–50	12 weeks	291	Xerostomia Fatigue Nausea	Stabilization
27/M	Abdomen Pelvis	50	6 weeks	229	Xerostomia Fatigue	Progression

Of these five patients, two exhibited partial tumor responses, one has stable disease, and two showed tumor progression.

Pharmaceutical Compositions and Modes of Administration of Gossypol and Related Compounds

The method of the present invention includes the administration of gossypol, gossypol acetic acid, or gossypolone, alone or in combination with one another and/or other conventional chemotherapeutic agents, and a pharmaceutically acceptable excipient, to a human subject.

In the methods according to the present invention pharmaceutical compositions containing compounds according to the present invention are administered in an effective amount to a human host for the treatment of a variety of human cancers including adrenal, ovarian, thyroid, testicular, pituitary, prostate, and breast cancer.

In administering gossypol and related compounds for the treatment of cancer by the methods of the present invention, certain pharmaceutical compositions, doses, routes of administration, and desired blood levels may be employed. These are summarized in the table below. In each case, the indicated dose and blood level are approximate, e.g., for oral administration of gossypol acetic acid(+)-compressed tablet, the dose may be from about 40 to about 100 mg/d, and the desired blood level may be from about 400 to about 800 ng/dl.

TABLE 4

Pharmaceutical Formulations, Doses, Routes of Administration, and Effective Blood Levels of Gossypol and Related Compounds for the Treatment of Human Cancer.

Formulation	Route	Dose	Blood Level
Gossypol acetic acid (+)—compressed tablet	Oral	40–100 mg/d	400–800 ng/dl
Gossypol acetic acid (+)—suppositories	Rectal, vaginal	40–140 mg/d	400–1000 ng/dl
Gossypol(+)—PVP and physiologic salts	Parent-eral	1–2 mg/kg/d	400–1000 ng/dl
Gossypol acetic acid (±)—compressed tablet	Oral	40–100 mg/d	400–800 ng/dl
Gossypol acetic acid (±)—suppositories	Rectal, vaginal	40–140 mg/d	400–1000 ng/dl
Gossypol(±)—PVP and physiologic salts	Parent-eral	1–2 mg/kg/d	400–1000 ng/dl
Gossypol(−)—tablet	Oral	20–100 mg/d	200–1000 ng/dl
Gossypol(−)—suppositories	Rectal	40–140 mg/d	200–1000 ng/dl
Gossypol(−)—PVP and physiologic salts	Parent-eral	1–2 mg/kg/d	200–1000 ng/dl

TABLE 4-continued

Pharmaceutical Formulations, Doses, Routes of Administration, and Effective Blood Levels of Gossypol and Related Compounds for the Treatment of Human Cancer.

Formulation	Route	Dose	Blood Level
Gossypolone tablet	Oral	50–200 mg/d	400–1000 ng/dl
Gossypolone suppositories	Rectal, vaginal	50–200 mg/d	400–1000 ng/dl
Gossypolone PVP and physiologic salts	Parent-eral	1–5 mg/kg/d	400–1000 ng/dl

When administered orally, the drug may be taken in divided doses, two to three times a day.

The invention being thus described, it will be obvious that the same may be varied in many ways. Such variations are not to be regarded as a departure from the spirit and scope of the invention, and all such modifications as would be obvious to one skilled in the art are intended to be included within the scope of the following claims.

What is claimed:

1. A method for treating a cancer in a human, wherein the cancer is susceptible to treatment with gossypol, a physiologically acceptable salt of gossypol, gossypolone, a physiologically acceptable salt of gossypolone, or any combination thereof, which method comprises:

administering to said human an anti-cancer effective amount of at least one compound selected from the group consisting of gossypol, a physiologically acceptable salt of gossypol, gossypolone, and a physiologically acceptable salt of gossypolone, and a pharmaceutically acceptable carrier.

2. The method of claim 1, wherein said cancer is adrenal, ovarian, thyroid, testicular, pituitary, prostate, or breast cancer.

3. The method of claim 2, wherein said cancer is adrenal cancer.

4. The method of claim 1, wherein the blood concentration of said compound is 400–1000 ng/dl.

5. The method of claim 4, wherein said compound is gossypolone or a physiologically acceptable salt of gossypolone.

6. The method of claim 5, wherein said gossypolone or physiologically acceptable salt of gossypolone is administered orally, rectally or vaginally at a dose of 50–200 mg/d.

7. The method of claim 5, wherein said gossypolone or physiologically acceptable salt of gossypolone is administered parenterally at a dose of 1–5 mg/kg/d.

8. A method for treating a cancer in a human, wherein the cancer is susceptible to treatment with gossypol, a pharmaceutically acceptable salt of gossypol, or a combination thereof, which method comprises:

administering to said human an anti-cancer effective amount of at least one compound selected from the group consisting of gossypol and a physiologically acceptable salt thereof, and a pharmaceutically acceptable carrier.

9. The method of claim 8, wherein said cancer is adrenal, ovarian, thyroid, testicular, pituitary, prostate or breast cancer.

10. The method of claim 8, wherein said cancer is adrenal cancer.

11. The method of claim 8, wherein the blood concentration of said compound is 400–1000 ng/dl.

12. The method of claim 8, wherein said compound is administered parenterally at a dose of 1–2 mg/d.

13. The method of claim 8, wherein said compound is administered orally at a dose of 20–100 mg/d.

14. The method of claim 8, wherein said compound is administered rectally at a dose of 40–140 mg/d.

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